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DEPARTMENT OF HEALTH & HUMAN SERVICES
Food and Drug Administration
New England District

Food and Drug Administration
One Montvale Avenue
Stoneham, Massachusetts 02180
(781)279-1675 FAX: (781)279-1742

WARNING LETTER

VIA CERTIFIED MAIL
RETURN RECEIPT REQUESTED

NWE -11- 98 W

May 26, 1998

Katsumi Oneda
President
Vision Sciences, Inc.
6 Strathmore Road
Natick, MA 01760

Dear Mr. Oneda:

During an inspection of your firm located in Natick, MA on April 27 through May 1, 1998, our Investigator determined that your firm is responsible for the manufacture and distribution of medical devices, including the S-F100 Sigmoidoscope and the SS-F32 EndoSheath System. These products are medical devices as defined by Section 201(h) of the Federal Food, Drug, and Cosmetic Act (the Act).

The above stated inspection revealed that these devices are adulterated within the meaning of Section 501(h) of the Act, in that the methods used in, or the facilities or controls used for manufacturing, packing, storage, or installation are not in conformance with the Quality System Regulations, as specified in Title 21 Code of Federal Regulations, (21 CFR) Part 820, as follows:

1. Failure to have an adequate corrective and preventive action system which allows for the analysis of service records, complaints, returned product and other quality data using a statistical methodology to detect recurring product quality. Your system also fails to investigate the cause of nonconformities and fails to verify that the corrective or preventive action taken, is effective. Your system also fails to ensure that information

related to quality problems or nonconforming product is disseminated to those directly responsible for assuring the quality of the product. For example:

- Your corrective and preventive action SOP, QSP#4.14, states that the Quality Manager will perform trending of all complaints to identify appropriate corrective actions if necessary. During the inspection, trending was not being done on any complaints or nonconformances. It was noted during the inspection that your firm has received a total of [redacted] complaints in 1997 and 1998 on [redacted] units that are currently in the field.

- This SOP also states that the complaint program the internal audit program and the Material Review Board (MRB) program (and also manufacturing and customer service) are all reviewed and the information from these reviews are made available to appropriate individuals to ensure that corrective or preventive action takes place. There was no indication that this is taking place. For example, on 3/31/98, part number C00440- an insertion tube was accepted with a use as is designation on a nonconformity report, (NCR). This component failed two specifications, the height range and the stiffness value. It was noted during the inspection that there were at least two previous records (service record RGA # 1703 S/N 93031 and complaint RGA #1730 S/N A0010C) that involved this actual component, however, the documentation to accept this component did not include any scientific rationale to accept this product which failed its incoming specifications. The NCR report also did not note that a corrective action was necessary.

2. Failure to review, evaluate and investigate complaints involving the possible failure of a device. For example:

   - Your complaint SOP, #037, states that an investigation shall follow-up all complaints. It also states that minimal requirements for an investigation will include, a review of the device history files for the product. During the inspection a total of [redacted] complaints were reviewed. There was no documentation in the file to indicate that a complete failure investigation was performed as per your SOP and none of these complaints had documentation that a review of the history records was performed. One complaint, RGA #1673, noted that the unit, S/N A0140C had been sent in twice before with the same problem.

This letter is not intended to be an all-inclusive list of deficiencies at your facility. It is your responsibility to ensure adherence to each requirement of the Act and regulations. The specific violations noted in this letter and in the FDA-483 issued at the close-out of the inspection may be symptomatic of serious underlying problems in your firm's manufacturing and quality assurance systems. You are responsible for investigating and determining the causes of the violations identified by the FDA. If the causes are determined to be systems problems, you must promptly initiate permanent corrective action.

Federal agencies are advised of the issuance of all Warning Letters about devices so that they may take this information into account when considering the award of contracts. Additionally, no premarket submissions for devices to which the GMP deficiencies are reasonably related will be cleared until the violations have been corrected. Also, no requests for Certificates For Products For Export will be approved until the violations related to the subject devices have been corrected.

You should take prompt action to correct the deviations discussed in this letter. Failure to promptly correct these deviations may result in regulatory action by the Food and Drug Administration without further notice. These actions include, but are not limited to, seizure, injunction and/or civil penalties.

Please notify this office within fifteen (15) days of receipt of this letter, of the specific steps you have taken to correct the noted violations, including an explanation of each step being taken to prevent the recurrence of similar violations. Your response should be sent to Karen N. Archdeacon, Compliance Officer, United States Food and Drug Administration, One Montvale Avenue, Stoneham, Massachusetts 02180.

Please note that we have received your letter dated May 7, 1998 in which you promise a more detailed response to the FDA 483 observations noted during the inspection.

If you have any questions concerning this matter, please contact Ms. Archdeacon at 781-279-1675, Extension 113.

Sincerely yours,

John R. Marzilli
District Director
New England District Office